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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,292	11/13/2001	David James Squirrell	41577/266329	5898

23370 7590 09/23/2003

JOHN S. PRATT, ESQ  
KILPATRICK STOCKTON, LLP  
1100 PEACHTREE STREET  
SUITE 2800  
ATLANTA, GA 30309

EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/23/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/009,292	SQUIRRELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Louise N. Leary	1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

1. Claims 1-22 are pending in this application. Claim 23 has been canceled per applicant's request filed June 24, 2003.
2. The rejection of claims 1-23 under 35 USC 112, second paragraph, has been withdrawn in view of applicant's amendment filed June 24, 2003.
3. The rejection of claims 1-23 under 35 USC 103(a) as unpatentable over Squirrell (US 5,648,232) in view of Webster's Dictionary (1984) has been maintained for reasons of record.
4. Applicant's arguments filed June 24, 2003 have been fully considered but they are not persuasive.

The examiner has carefully considered applicant's traversal of the rejection but respectfully disagree with applicant's assertion that "[I]n contrast to the present invention, the '232 and '214 patents merely describe a method for detecting the presence and/or amount of microorganisms in a sample by lysing the microorganisms with, for example, detergent or mechanical means and detecting the amount of ATP in the sample after adding ADP thereto. The '214 patent includes the additional step of binding any adenylate kinase present in the sample to a binding agent prior to the addition of ADP. There is no teaching or suggestion anywhere in either the '232 or the '214 patent that the assays describe therein could be used for any other purpose than detecting the presence or amount of a microorganism in a sample. More importantly, there is

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no teaching or suggestion that the methods described in the '232 and '214 patents could be used to determine the cell integrity of a eukaryotic cell subjected to test conditions.]" The examiner disagrees because in regards to the use of eukaryotic cells in the instant enzymatic assays, Squirrell discloses :

(I) "All living microorganisms utilize adenosine triphosphate (ATP) as a source of chemical energy and it is known to assay this using the ATP driven luciferase/luciferin reaction. Light generated by this enzymatic reaction can be measured using a luminometer and related to the amount of ATP present." See column 1, lines 15-19; and

(II) "[Usually for assaying microorganisms only cationic detergent is needed, whereas if fungal spores and eucaryotic, eg. somatic, cells ape likely to be significant then a further nonionic detergent reagent might be included to asses their numbers. The kit is in the form of a single package preferably including instructions as to how to perform the method of the invention;...]" Note column 6, lines 48-54.

In addition, while the Squirrell reference dose not use the phrase "eukaryotic cell integrity", the Squirrell reference does provide sufficient guidance in the kit instructions as to how to perform the assay method when eukaryotic cells in a sample are to be assayed. Further, as noted in the previous office action on the merits, Webster's Dictionary defines "microorganisms" as "[an animal or plant of microscopic size, esp. a bacterium or protozoan.]" Webster's Dictionary also defines ["eukaryote" as an organism having one or more cells with well-defined nuclei"]. Again, it is noted that persons having ordinary skill in

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this art at the time this invention was made included viable nucleated cells in the definition of "microorganisms".

Therefore, the rejection of claims 1-22 has been maintained because the Squirrell disclosure in view of Webster's Dictionary definitions of "microorganism" and "eukaryote" rendered obvious the instant assay methods and kits at the time this invention was made. For these reasons, the rejection under 35 USC 103(a) has been maintained.

**5. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday from Monday to Friday to 10am to 6:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Buyback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



LOUISE N. LEARY  
PRIMARY EXAMINER

September 22, 2003